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EXAMINER

BARHAM, BETHANY P

ART UNIT

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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/547,068 | Applicant(s) FOTINOS ET AL. | |
| | Examiner BETHANY BARHAM | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 113-146 is/are pending in the application.
- 4a) Of the above claim(s) 115-118 and 126-146 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113, 114 and 119-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/25/05, 1/27/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of IDS filed on 8/25/05 and 1/27/06 is acknowledged. Claims 113-146 are pending.

Election/Restrictions

Applicant's election of Group I in the reply filed on 7/20/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant states in their response that "the examiner has not explained why each group lacks unity with each other group", however the Examiner respectfully disagrees and as the restriction clearly pointed out that the feature each group shares is a patch with the technical feature of "volatile containing active layer, a barrier layer attached to the active, a fractional adhesion layer and a release liner/layer" and further pointed out the differences between the groups that group II also contained "a mask layer with first and opposite sides", Group III "including an intermittent mask layer" and Group IV a method of making, but there was no special technical feature amongst the groups. US 4,874,129 Figures 6-16, which teaches a common technical feature of a volatile containing active, a barrier or backing layer, an adhesive and a release layer in a patch wherein the layers can be rearranged in various forms, no further teaching is needed as the technical feature is not special under PCT Rule 13.1

Art Unit: 1615

states the inventions listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the inventions lack the same or corresponding special technical features. As such, claims 115-118 and 126-146 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Claims 113-114 and 119-125 will be examined in the instant application. The requirement is still deemed proper and is therefore made FINAL.

NEW OBJECTIONS/REJECTIONS

Claim 114 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 114 does not further limit and is a substantial duplicate of a portion of claim 113 from which it depends.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 113 and dependent claims thereon are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Currently the instant claims recites the limitation of "the fractional adhesion layer comprising an adhesion

Art Unit: 1615

area that is a fraction of the total area of a side of the barrier layer”, which is indefinite.

What are the metes and bounds of this claim? There is no upper or lower limit to the claim and it is indefinite, and as such the Examiner will examine the claims as reading on any fraction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 113-114, 119, and 122 are rejected under 35 U.S.C. 102(a)/(e) as being anticipated by US 2002/0160035 ('035).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102 (a)/(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

Art Unit: 1615

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claims are drawn to a patch having reduced adhesion for delivering a volatile substance, the patch comprising: an active layer comprising the volatile substance; a barrier layer having a first side and an opposite side, the first side attached to the active layer; a fractional adhesion layer adjacent to an opposite side of the barrier layer from the active layer, the fractional adhesion layer comprising an adhesion area that is a fraction of the total area of a side of the barrier layer; and a release liner covering the adhesion area adjacent to the opposite side of the barrier layer.

- '035 teaches a patch that delivers a volatile substance and Fig 1 teaches a volatile active layer (3), a barrier layer (4), an adhesive layer (2), and a release liner (5), wherein the release liner cover the adhesive layer which is next to (or adjacent) the barrier layer with the active on the other side of the barrier layer (abstract, Fig 1, [0038-0039, 0041-0042, 0046-0047]) (meeting the limitations of claim 113-114). From Fig. 1 it can be seen that the adhesive layer covers only a fraction of the barrier layer.
- '035 teaches that the active layer is a solid and contains polymers like gelatin, hydroxypropylcellulose, etc [0011, 0051, 0055] (meeting the limitations of claim 119).
- '035 teaches volatile substances include insect repellant, deodorizers, aromatherapy, essential oils, etc [0018, 0030] (meeting the limitations of claim 122).

Claims 113-114, 119 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,874,129 ('129).

- '129 teach in Figs. 6 and 8 for example a patch with an active layer, a rate controlled polymer/backing layer, an adhesive layer, and a release layer, which contains fragrance oil (abstract, Figs. 6-16). From Fig. 6 it can be seen that the adhesive layer only cover a portion of the barrier layer (meeting the limitations of instant claims 113-114 and 122).
- '129 teaches that the fragrance active is in a silicone matrix (abstract, Examples) (meeting the limitations of claim 119).

Claims 113-114 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,915,950 ('950).

- '950 teach in Figs. 1 for example a patch with an active layer on one side of the adsorbent layer, an adhesive layer, and a release/backing layer (abstract, Figs. 1) (meeting the limitations of instant claims 113-114).
- '950 teaches the use of volatile substances such as nicotine, nitroglycerin, scopolamine, etc (col. 7, lines 34-44) (meeting the limitations of claim 122).

Claims 113-114, 119 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,352,456 ('456).

Art Unit: 1615

- '456 teaches a transdermal drug delivery device that administers drugs comprising a drug reservoir with a drug dissolved in a carrier and a volatile permeation enhancer, a substrate layer, an adhesive layer and a release liner (abstract, Fig. 1). Drugs such as scopolamine, etc are taught (col. 2, lines 35-46) (meeting the limitations of 113-114 and 122).
- '456 teaches that the reservoir layer contains carriers such as silicone (col. 5, line 6) (meeting the limitations of claim 119).

Claims 113-114, 119-120, 122 and 124-125 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,071,704 ('704).

- '704 teaches a controlled release device for the release of vapors or liquid which is multilayered with a reservoir layer containing the active such as a perfume, fragrance, insect repellent, a diffusion layer, an adhesive layer and an impermeable membrane (abstract, col. 6, lines 10-20) (meeting the limitations of instant claims 113-114 and 122).
- '704 teaches that the reservoir layer contains a porous polymer or foam with cell sizes with a porosity from about 0.1-0.8, such as polyurethanes and that the active compound and polymer can form a system where the particulates of the compound are dispersed throughout the polymer (col. 4, lines 30-43) (meeting the limitations of instant claims 119-120 and 124-125).
- Note giving the claims the broadest reasonable interpretation the prior art teaching of a porous, or foam with cell sizes and porosity from about 0.1-0.8

Art Unit: 1615

reads on the instant claims "high specific surface area" and "bubbles" as instant claimed in claims 124-125.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 113-114, 119-122 and 124-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,071,704 ('704) in view of US 2003/0007944 ('944) or US 2003/0118533 ('533).

- '704 is taught above and teaches a controlled release device for the release of vapors or liquid which is multilayered with a reservoir layer containing the active such as a perfume, fragrance, insect repellent, a diffusion layer, an adhesive layer and an impermeable membrane (abstract, col. 6, lines 10-20) (meeting the limitations of claims 113-114, 119-120, 122 and 124-125).
- '704 does not teach polyurethane-1 of instant claim 121, but does teach the reservoir layer containing a polyurethane.
- '944 teaches film forming compositions for application to the skin containing polyurethane, preferably polyurethane-1 (abstract) (meeting the limitations of claims 121).

Art Unit: 1615

- '533 teaches topical compositions for patches including polymers such as Luviset or polyurethane-1 [0023, 0026].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the specific polyurethane-1 of '944 or '533 into the composition of '704. Simple substitution of one polyurethane of '704 for another of '944 or '533 is within the purview of the skilled artisan and would yield predictable results.

Claims 113-114, and 119-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,352,456 ('456), US 4,874,129 ('129) or US 2002/0160035 ('035) in view of US 2003/0007944 ('944) or US 2003/0118533 ('533).

- '129 or '035 is taught above and teaches a controlled release device for the release of vapors or liquid which is multilayered with a reservoir layer containing the active such as a perfume, fragrance, insect repellent, a diffusion layer, an adhesive layer and an impermeable membrane (meeting the limitations of claims 113-114, 119, and 122).
- '129 or '035 do not teach polyurethane-1 of instant claim 121, but do teach the reservoir layer containing a polymer such as silicone or gelatin.
- '944 teaches film forming compositions for application to the skin containing polyurethane, preferably polyurethane-1 (abstract) (meeting the limitations of claims 121).
- '533 teaches topical compositions for patches including polymers such as silicones, Luviset or polyurethane-1 [0023, 0026].

Art Unit: 1615

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the specific polyurethane-1 of '944 or '533 into the composition of '129 or '035. Simple substitution of one film forming polymer of '129 or '035 for another of '944 or '533 is within the purview of the skilled artisan and would yield predictable results.

Claims 113-114, 119-120 and 122-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,071,704 ('704), US 4,915,950 ('950), US 5,352,456 ('456), US 4,874,129 ('129) or US 2002/0160035 ('035) in view of US 5,589,122 ('122) or US 6,129,983 ('983).

- '704, '950, '456, '129, or '035 are taught above and teach a patch for the release of vapors or liquid which is multilayered with a reservoir layer containing the active such as a perfume, fragrance, insect repellent, a diffusion/barrier/controlled release layer, an adhesive layer and an impermeable membrane (abstracts) (meeting the limitations of claims 113-114, 119-120, 122 and 124-125).
- '704, '950, '456, '129, or '035 do not teach "the barrier layer is a double coated tape, each side of the double coated tape covered with an adhesive layer" of instant claim 123, but do a diffusion/barrier/controlled release layer.
- '122 teaches double-sided adhesive tape which has adhesive layers on two sides, typically with a layer in between the adhesive tapes and the method of making such tapes (abstract, col. 1, lines 13-15; col. 2, lines 43-55; Fig. 1).

Art Unit: 1615

- '983 teaches a double-sided self-adhesive tape comprising a layer that is coated on both sides with adhesive compositions and methods of making such double-sided tapes (abstract, col. 3, lines 62-col. 4, lines 18)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the known method of making a layer comprising a double sided adhesive tape of '122 or '983 into the known multilayered patch compositions of '704, '950, '456, '129, or '035. Combination of a known product (ie patch) of '704, '950, '456, '129, or '035 with a known technique (ie a method of making a layer a double-sided adhesive tape) of '122 or '983 is within the purview of the skilled artisan and would yield predictable results.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615